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APPENDIX A **510(K) SUMMARY**

Baby Dopplex® 3000 Mk2

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Name of Device: **Baby Dopplex® 3000 (BD3000 Mk2)**

Manufactured by: Huntleigh Diagnostics Ltd
35, Portmanmoor Road,
Cardiff
South Glamorgan CF24 5HN
Wales, U.K.

Contact Person at Manufacturing Facility:

B.J.Colleypriest
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Date Special 510(k) prepared: **19 March 2001**

Classification Name

Fetal Ultrasonic Monitor and Accessories (21 CFR § 884.2660)

Predicate Devices

Baby Dopplex 4000 (BD4000) K990569 & K001677

Device Description

The BD3000 Mk2 is a mains powered antepartum/intrapartum fetal monitor that produces fetal cardiotocographs (CTG) from received ultrasonic and electrical impulses. It is based on the predicate BD4000 (K990569 & K001677) with some of the available features on the predicate device not being implemented into the applicant device.

The medical practitioner or clinician uses the BD3000 Mk2 as one of the indicators when assessing fetal well being. The unit can be used by the trained clinician in hospital or community situations. The device is designed for desktop or trolley mounted use, or can be wall mounted.

The device is intended for use from a gestation age of approximately 26 weeks.

Key Differences To The Predicate BD4000

The following lists the key features that have been removed from the BD4000 in implementing the BD3000 Mk2:

- Serial ports – these and all associated features are not available
- Twins monitoring – this facility has been removed
- Alarms monitoring – this facility has been removed
- FECG and IUP transducers / optional accessories – these facilities have been removed
- User manual – will be specific for the BD3000 Mk2 product

Patient Category

The BD3000 Mk2 is suitable for use in all conventional fetal monitoring applications viz.:

- Antenatal monitoring in the health clinic, home or community.
- Hospital admission tests.
- External Labour monitoring.

The BD3000 Mk2 is not suitable for the following uses: -

- Underwater monitoring during labour or delivery.
- Monitoring in any environment where the patient or user is likely to come into contact with water.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Huntleigh Healthcare, Inc.
c/o Mr. B. J. Colleypriest
Technical Co-ordinator
Huntleigh Diagnostics Ltd.
35 Portmanmoor Road, Cardiff.
CF24 5HN
UNITED KINGDOM

Re: K010889
Baby Dopplex® 3000 Mk2
Dated: March 22, 2001
Received: March 26, 2001
Regulatory Class: II
21 CFR §884.2740/Procode: 85 HGM

Dear Mr. Colleypriest:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

APPENDIX C INDICATIONS FOR USE

510(k) Number K010889

Device Name: **Baby Dopplex® 3000 Mk2**

Indications for Use

The BD3000 Mk2 is a mains powered antepartum fetal monitor that produces fetal cardiotocographs (CTG) from received ultrasonic and electrical impulses

The medical practitioner or clinician uses the BD3000 Mk2 as one of the indicators when assessing fetal well being.

The device is intended for use from a gestation age of approximately 26 weeks.

Fetal movement detection is also monitored by processing the received Doppler signals.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the counter use _____

(Per 21 CFR 801.109)

David C. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010889